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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,598	03/21/2002	Akio Yamane	2002-0401A	6872

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EXAMINER	
SAKELARIS, SALLY A	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 05/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,598	YAMANE, AKIO	
	Examiner	Art Unit	
	Sally A. Sakelaris	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2004*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 2/4/2005 has been entered.

This action is written in response to applicant's correspondence submitted 2/4/2005. Claim 1 has been amended and claim 10 has been added. Claims 1-3 and 5-10 are pending. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn as necessitated by applicant's amendments to the claims. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

Acknowledgement of claim to foreign priority of Japanese Application, 11/268745, filed 9/22/1999 under 35 U.S.C. 119(a)-(d) has been made, however applicant should note that while the certified copy was received 2/4/2005 the translation of this foreign priority document has not yet been received and as a result the claim to foreign priority under the same has not yet been granted.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-3 and 5-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Livak et al.(US Patent 5,723,591)

With regard to claim 1, Livak et al. teach a probe comprising a nucleic acid carrying a labeling substance that releases energy and an energy-absorbing substance capable of absorbing the energy(quencher) which is capable of specifically binding to a double-stranded nucleic acid, wherein the energy absorbing substance is capable of absorbing the energy released from the labeling substance, wherein the energy-absorbing substance specifically interacts with the double stranded nucleic acid due to the hybridization of the probe with a target nucleic acid thereby resulting in no quenching of the labeling substance. The reference further teaches the probe wherein energy transfer from the labeling substance to the energy-absorbing substance is intercepted by the hybridization of the probe with a target nucleic acid, in their teaching of an oligonucleotide probe "which includes a fluorescent reporter molecule and a quencher molecule capable of quenching the fluorescence of the reporter molecule"(abstract and for example Figure 1 and claim 1). The reference goes on to teach that "the oligonucleotide probe is constructed such that the probe exists in at least one single-stranded conformation when unhybridized where the quencher molecule is near enough to the reporter molecule to quench the fluorescence of the

reporter molecule". "The oligonucleotide probe also exists in at least one conformation when hybridized to a target polynucleotide where the quencher molecule is not positioned close enough to the reporter molecule to quench the fluorescence of the reporter molecule"(Abstract).

With regard to claim 2, Livak et al. teach that "the reporter molecule and quencher molecule are positioned on the probe sufficiently close to each other such that whenever the reporter molecule is excited, the energy of the excited state nonradiatively transfers to the quencher molecule where it either dissipates nonradiatively or is emitted at a different emission frequency than that of the reporter molecule"(Col. 3 lines 3-8).

With regard to claim 3, Livak et al. teach that the labeling substance is a fluorescent substance and "may be selected from xanthene dyes, including fluoresceins, and rhodamine dyes"(Col. 11 lines 22-23).

With regard to claims 5 and new claim 10, Livak et al. teach that the energy absorbing(quencher) is an intercalator or a substance which specifically binds to a double stranded nucleic acid, in Col. 11 in their teachings of exemplary reporter-quencher pairs and dyes including acridines like acridine orange, "pyrenes and the like"(lines 33-35).

With regard to claim 6, Livak et al. teach that the labeling substance "may be selected from xanthene dyes, including fluoresceins, and rhodamine dyes"(Col. 11 lines 22-23). While Livak et al. also teach that the energy absorbing(quencher) may be selected from another group of fluorescent compounds including acridines like acridine orange, "pyrenes and the like"(lines 33-35).

With regard to claim 7, Livak et al. teach "according to one embodiment of the method, the hybridization probe is immobilized on a solid support"(Col. 8, lines 38-50). "The

oligonucleotide probe is contacted with a sample of nucleic acids under conditions favorable for hybridization". "The fluorescence signal of the reporter molecule is measured before and after being contacted with the sample. Since the reporter molecule on the probe exhibits a greater fluorescence signal when hybridized to a target sequence, an increase in the fluorescence signal after the probe is contacted with the sample indicates the hybridization of the probe to target sequences in the sample". "Immobilization of the hybridization probe to the solid support enables the target sequence hybridized to the probe to be readily isolated from the sample"(Col. 8 and claim 16).

With regard to claims 8 and 9, as stated above, Livak et al. teach that "the present invention relates to the use of the oligonucleotide probe as a hybridization probe to detect target polynucleotides"(Col. 5 lines 39-60). Further that "quantification of the change in fluorescence intensity as a result of the probe being contacted with the sample can be used to quantify the amount of target sequences present in the sample"(Col. 5 lines 55-58).

Response to Arguments

Applicant's arguments filed 2/8/2005 have been fully considered but they are not persuasive. Applicant first argues that "the office's characterization of the claimed invention is inaccurate" as claim 1 as amended requires that the energy absorbing substance "interacts with the double-stranded nucleic acid due to the hybridization of the probe of [with] the target nucleic acid thereby resulting in no quenching". Applicant asserts that "due to" requires the sequential order of steps of hybridization, interacting and no quenching. First, it is not the opinion of the examiner that "due to" limits the claim to these sequential steps. Second, it is maintained that the probe of Livak does meet applicant's limitation of interacting with the double stranded

nucleic acid due to hybridization of the probe...no quenching. The limitation "interaction with the double-stranded nucleic acid" is met seeing as the quencher via the probe interacts with the nucleic acid. In addition the limitation "resulting in no quenching" is also met by Livak as ultimately this association does result in no quenching to occur. Again applicant should note that the office must read the claims as broadly as they are written and that they need to require specifically those limitations that they argue. Limitations in applicant's arguments, specification etc cannot be read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, without a requirement for the interception to result in no quenching, or a requirement for a hybridization step to necessitate the interception, the art will be applied as broadly as the claims are written. The courts have stated that claims must be given their broadest reasonable interpretation consistent with the specification *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997); *In re Prater*,415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969); and *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (see MPEP 2111).

Next, applicant argues "Livak's invention is structurally different in that it involves a conformational change not found in the present invention". Applicant's additional statement that "the claim language of the instant application precludes the invention in Livak" is not deemed accurate by the examiner. The claims as written do not preclude a probe that undergoes a conformational change to accomplish the same goal as one that does not. There is no recitation in the claims of this limitation. Further, applicant should note that the examiner is not suggesting any change to the claim that would require the inclusion of new matter into applicant's claim. However, as presently written applicant's argued novelty of a probe whose "interaction and

subsequent interception" causes no quenching to occur is not being recited in the pending claims. As a result it is maintained that the presently cited art does fully anticipate the presently claimed invention for the reasons stated above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sally A. Sakelaris whose telephone number is 571-272-0748. The examiner can normally be reached on M-Fri, 9-6:30 1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sally Sakelaris
4/29/2005

W. Gary Jones
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